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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,424	04/19/2000	Luke V. Schneider	020444-000400US	3984

20350 7590 03/26/2003

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/26/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,424

Applicant(s)

SCHNEIDER, LUKE V.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

This Office Action is in response to the election filed 9 January 2003. The election of Group I is acknowledged. Upon due reconsideration, the previously made requirement for restriction under 35 USC 121 is vacated in favor of the following requirement for restriction:

- Group I Claims 1- 26 and 36-38, drawn to method for analyzing metabolic pathway comprising administering to a subject a isotope-labeled substrate and determining the isotope abundance of metabolized substrate, classified in class 424, subclasses, 1.11, 1.37, 1.45, 1.65, 1.69, 1.73 and 1.77, class 514, subclasses 2, 44, 557 and 558, class 436, subclasses 173 and 174, class 435, subclasses 6 and 7.1, class 604, subclass 504, and class 204, subclasses 450 and 456.
- Group II Claims 27-35, drawn to method for screening for metabolites correlated with a disease and presence of the disease state comprising administering to a subject a isotope-labeled substrate, determining the isotope abundance of metabolized substrate and comparing a flux value of a target analyte from the control subject to that from the test subject, classified in class 424, subclasses, 1.11, 1.37, 1.45, 1.65, 1.69, 1.73 and 1.77, class 514, subclass 1⁺, subclasses 6 and 7.1, class 604, subclass 504, and class 204, subclasses 450 and 456.

The inventions are distinct, each from the other for the following reasons:

Invention I and invention II are directed to different and/or distinct methods, a method of analyzing metabolic pathway that is uncorrelated with disease state and a method of screening for metabolites correlated with a disease and presence of the disease state. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Invention II and III since they constitute patentably distinct inventions comprising methodologies (physiological or pathological states), starting material, objectives, clinical considerations (*e.g.*, disease state), ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Additional Election Under 35 USC 121

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed

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37 C.F.R. 1.143). In the response, applicant is to indicate (1) the elected group and indicate (2) the further election as required below.

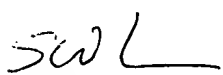
If Group I is elected, applicant is required to elect one substrate, protein, or carbohydrate, or polynucleotide, or amino acid, or nucleotides, or nucleoside, or fatty acid, or organic acid or fat molecule from claims 10 and 16, since each molecule is structurally distinct/different from one another. Also, applicant is required to elect one spectrometric mean from claims 21 and 38, respectively, for examination because each mean has distinct/different operative mechanisms and procedures as well as sample preparatory requirements.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Samuel W. Liu, Ph.D.
March 24, 2003


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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